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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,856	06/29/2001	Joffre Baker	P0894P1D2C4	9045

9157 7590 05/23/2003

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/896,856	Baker et al
Examiner	**Art Unit**
Robert C. Hayes, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 4, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *31-34, 41, and 42* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *31-34, 41, and 42* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(d) states that each sequence disclosed must appear separately in the "Sequence listing", and referenced appropriately *in the text of the description* and the *claims*. See MPEP 2422 & 2431. In other words, pages 5 (lines 28, 30 & 34), 6 (line 30), 9 (lines 28, 29 & 32), 11 (line 5), 12 (lines 29 & 30), 26 (lines 19 & 28), 27 (lines 3 & 4), 29 (line 36), 33 (line 32) and 66 (lines 34 & 35) need to be amended to list the sequences being discussed. Note that any response not placing this application in compliance with the SEQUENCE RULES will be held as non-responsive.

2. The amendment filed 3/04/03 has been entered.

3. The rejection of claim 41 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claim.

4. The rejection of claim 33 & 38-40 under 35 U.S.C. 112, first paragraph, for new subject matter is withdrawn due to either the cancellation of the claims or after reconsideration by the Examiner.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Applicant's arguments filed 3/04/03 have been fully considered but they are not deemed to be persuasive.

7. Claims 31-34 & 41-42 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing survival of motor neurons or embryonic chick ciliary neurons with CT-1 of SEQ ID Nos: 3 or 8, does not reasonably provide enablement for any *in vivo* method for generically treating any *generic neuronal* population with structurally *and functionally* uncharacterized CT-1 polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 8 (mailed 9/05/02) and as follows.

Applicants argue on pages 4-5 of the specification that "Applicants point out the need for other agents like CNTF for increasing neuronal survival and then go to show similarity of CT-1

and CNTF behavior in the CNTF assay". However, the state of the art for treating neurons *in vivo* with CNTF is as illustrated by Sendtner (see Barinaga, 1994) who found that the neurotrophic factor CNTF is quickly taken up and degraded by the liver with a half life of 3 minutes. Moreover, in this same publication it was reported (same column on pg. 773) that Regeneron's Phase III study on CNTF to treat ALS resulted in a substantial number of those receiving CNTF having not only serious side effects, but having actually fared worse on measures of muscle strength than did patients receiving placebos. Thus, because it is unclear how one could administer an effective dose of any CNTF-derived neurotrophin, and by Applicants' analogy a CT-1 polypeptide, for a sufficient time period to elicit any measurable response, because it is unknown or disclosed what route of administration is effective for using any such polypeptide *in vivo*, because it is unknown what distinct population of neurons (i.e., what neurons contain CT-1 receptors) are required to be assayed in order to determine when, or if, the instant invention is effective *in vivo*, and because it cannot be successfully extrapolated from the limited *in vitro* tissue cultures disclosed whether the skilled artisan has successfully practiced Applicant's invention, it would require undue experimentation to determine such, and for the reasons previously made of record.

Second, consistent with the teachings of Rudinger previously made of record, variants of the CT-1 polypeptide of SEQ ID NO: 3 or 8 would be predicted to result in CT-1 polypeptides with no "survival-promoting activity"; especially when such variants (i.e., as it relates to "sequence identity of at least 70%") have no such recited functional limitations. In other words,

merely amending the claims to "administering... an isolated biologically active polypeptide" fails to define the metes and bounds such molecules putatively possess, in which even denatured proteins are "biologically active" as it relates to the generation of antibodies, etc., which alternatively has nothing to do with the skilled artisan knowing how to practice the currently claimed method, for the reasons previously made of record.

8. Claim 34 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper No: 8 (mailed 9/05/02) and as follows.

As previously made of record, motor neurons are not neurons of the peripheral nervous system; thereby, being improperly dependent on base claim 32. Applicants' conclusion that "a motor neuron according to claim 34 is readily understood to be part of the peripheral nervous system" is simply incorrect, because the claims are not directed toward "parts of nerve cells", in which motoneuron cell bodies alternatively reside in the CNS, not the PNS; thereby, being part of the central nervous system, as previously made of record.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
May 19, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600